

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 1 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**REPLY IN SUPPORT OF MOTION TO EXCLUDE
GENERAL-CAUSATION TESTIMONY OF KIMBERLY H. ALLISON, M.D.**

The Court should exclude the testimony of Plaintiffs' pathology expert Dr. Kimberly H. Allison in its entirety. Plaintiffs offer Dr. Allison as a specific-causation expert, but Dr. Allison has not relied on any admissible general-causation testimony in formulating her specific-causation opinions, as she is required to do. Her specific-causation testimony is therefore unreliable and should be excluded, as explained below and in Ethicon's motions to exclude her case-specific opinions, which are incorporated here.

While Plaintiffs insist that they have not designated Dr. Allison as a general-causation expert, Ethicon nonetheless moves the Court to preclude Dr. Allison from testifying as to general causation. Plaintiffs repeatedly assert that Dr. Allison is not a general-causation expert, but then insist that she be allowed to testify to her "general opinions" underlying her case-specific opinions. Pls.' Mem. at 2–4. The Court should reject this argument because these general opinions are indistinguishable from general-causation opinions and Plaintiffs refused to allow Ethicon to take Dr. Allison's general-causation deposition, as it was entitled to do under both the Court's procedural orders and the parties' agreement. Plaintiffs cannot have it both ways—they

may not refuse to present Dr. Allison for a general-causation deposition and then insist that she be allowed to present general causation opinions at trial.

Regardless, even if the Court were to reject Ethicon's argument that it would be unfair and prejudicial to allow Dr. Allison to offer general-causation testimony in light of Plaintiffs' position, Dr. Allison's general-causation opinions are inadmissible because they are wholly unreliable. She offers opinions in this litigation that she admits she never offers in her practice. She bases her opinions on a non-scientific sample of pathology specimens hand-selected by plaintiffs' counsel. She cannot link her opinions that mesh degrades *in vivo* to any symptoms Plaintiffs allegedly suffered. She was unaware of alternative possible explanations for the degradation she believes she observed. And she has no scientific basis for her conclusion that the entrapped nerves she observed in Plaintiffs' tissue samples caused their pain, as she admits that she has no way of knowing if they are the type of nerves that are even capable of transmitting pain.

For these reasons and the reasons detailed in Ethicon's memorandum, Ethicon requests that the Court grant its motion to exclude Dr. Allison's general-causation testimony.

ARGUMENTS AND AUTHORITIES

I. The Court Should Preclude Dr. Allison from Testifying on General Causation Given Her Refusal to Sit for a General-Causation Deposition.

Ethicon's challenge to Dr. Allison is straightforward. An expert may not offer specific-causation opinions without first establishing that those opinions are supported by reliable general-causation testimony. Defs.' Mem. at 15–16 (citing, *inter alia*, *In re Mirena IUD Products Liab. Litig.*, No. 13-CV-6586 (CS), 2016 WL 890251, at *39 (S.D.N.Y. Mar. 8, 2016); *In re Rezulin Products Liab. Litig.*, 441 F. Supp. 2d 567, 578 (S.D.N.Y. 2006)); and *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 605 (S.D. W. Va. 2013)). In order to offer her specific-causation opinions, then, Dr. Allison must either support them with reliable general-causation opinions of

her own, or identify another expert's general-causation testimony that supports her specific-causation opinions. *Id.* This requirement has important ramifications for Dr. Allison's testimony, because she testified that she did not review any reports of any of Plaintiffs' experts; the only reports she read in these cases were those of *Defendants'* pathology experts. Defs.' Mem. at 16–17. This testimony establishes that the only general-causation opinions that could form a basis for her specific-causation testimony would be Dr. Allison's own.

But Plaintiffs precluded Ethicon from taking Dr. Allison's general-causation deposition, refusing to offer her for anything other than case-specific depositions, on the grounds that Dr. Allison has not been designated as a general-causation expert. *See* Defs.' Mem. at 3. Plaintiffs do not dispute this fact. *See* Pls.' Opp'n at 2–4. Instead, they argue that "Ethicon had more than sufficient time to examine her about the general principles in her report[,]" asserting that "Dr. Allison was not asked one question about the general sections of her report." *Id.* at 4. Plaintiffs do not cite to anything in the record to support this assertion, *id.*, and it is not for Plaintiffs to decide whether Ethicon had an adequate opportunity to explore Dr. Allison's general-causation opinions. Plaintiffs may not refuse to offer Dr. Allison for a general-causation deposition, then unilaterally determine that their refusal did not prejudice Ethicon. Based on Plaintiffs' refusal to present Dr. Allison for a general-causation deposition, the Court should preclude her from offering general-causation opinions. Denying Ethicon's motion and allowing Dr. Allison to testify as to general causation would be contrary to the Court's procedural orders and the parties' agreement, and would unfairly prejudice Ethicon.

Plaintiffs argue that Ethicon's motion here "has some similarity to the motion filed in relation to Dr. John Steege in *Huskey v. Ethicon, Inc.* where Ethicon sought to prevent Dr. Steege from testifying to the bases of his case-specific opinions, namely, degradation, shrinkage, chronic inflammation, etc." Pls.' Opp'n at 3 & n.6 (citing *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d

691, 713–17 (S.D.W. Va. 2014)). This is incorrect. Ethicon moved to exclude general-causation testimony of Dr. Steege, an obstetrician and gynecologist, for lack of “fit” to the facts of the case, based on his failure to examine Ms. Huskey’s explanted mesh. *Id.* at 714. Ethicon’s challenge to Dr. Steege’s specific-causation opinions was on the grounds that he did not have all of the relevant information from her medical history and failed to conduct a proper differential diagnosis. *Id.* Ethicon’s challenge here is not based on any of these grounds.

It is important that the Court rule on this issue since it is a necessary predicate for Dr. Allison’s specific-causation testimony. Ethicon therefore requests that the Court grant its motion to exclude Dr. Allison’s general-causation testimony, as well as its motions to exclude her case-specific testimony.

II. Dr. Allison’s General Causation Testimony Is Unreliable in Any Event.

As explained in Ethicon’s memorandum, Dr. Allison’s general-causation opinions are inadmissible in any event because they are unreliable. Defs.’ Mem. at 3–4. Plaintiffs’ arguments to the contrary are without merit.

A. Dr. Allison’s Litigation Opinions Are Not Supported by Her Clinical Experience.

Dr. Allison has reviewed few mesh explants outside the context of litigation. *Id.* at 4–6. And when she conducted those reviews, her focus was merely on confirming the identity of the explanted material—i.e., confirming that the material removed by the surgeon was, in fact, mesh. *Id.* She has never, in the course of her clinical practice, reviewed explanted mesh in order to formulate an opinion about whether or not the mesh caused a patient’s clinical symptoms, such as pain. *Id.* at 5. Ethicon noted these points in its memorandum because they establish that the opinions Dr. Allison developed in the course of this litigation are not opinions based on her day-to-day clinical practice—important support for the argument that Dr. Allison’s litigation-specific opinions are unreliable.

Plaintiffs' response to this argument is to argue Dr. Allison's qualifications. Pls.' Mem. at 4–6. Yet Dr. Allison's qualifications are not the issue—the challenge is to the reliability of her opinions. “Qualifications alone do not guarantee reliability,” as the *Sanchez* opinion Plaintiffs cite makes clear. *Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *6 (S.D.W. Va. Sept. 29, 2014)); *see also Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 680 (S.D.W. Va. 2014) (“Even though Dr. Margolis has experience, he must still base his opinion on a reliable, scientific method.”). Plaintiffs rely on *Wise* and *Sanchez*, Pls.' Opp'n at 6–7, but in the cited analyses, the Court evaluated Drs. Austin and Trepeta's qualifications, not the reliability of their opinions. *Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 570070, at *4 (S.D.W. Va. Feb. 11, 2015) and *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *20 (S.D.W. Va. Sept. 29, 2014), *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D.W. Va. Oct. 17, 2014). And despite its finding that Dr. Trepeta was qualified to offer his proposed testimony, the Court excluded much of it as unreliable. *See Sanchez*, 2014 WL 4851989, at *22 (excluding opinions derived from review of nonstatistical sample of pathology slides provided by plaintiffs); *id.* at *23–24 (excluding Dr. Trepeta's specific-causation opinions for failure to conduct a reliable differential diagnosis).

The Court should do the same here. Dr. Allison's clinical experience does not offer meaningful support for her opinions that the inflammation and supposed degradation that she observed in her review of the pathology is the cause of the clinical symptoms alleged by Plaintiffs. Defs.' Mem. at 4–7. And as explained in Ethicon's memorandum, and discussed further below, her admissions establish that she cannot support her conclusions with any scientifically valid data establishing this causal connection. *Id.* at 7–16. Her opinions are therefore unreliable and should be excluded.

B. Dr. Allison Cannot Base Her Opinions on Her Review of a Non-Statistical Pathology Sample.

To the extent that Dr. Allison would offer general-causation opinions regarding mesh degradation, they cannot be based on her review of the 60 to 90 pathology slides previously provided by plaintiffs’ counsel; as the Court has repeatedly acknowledged, these samples of pathological specimens were not selected using any statistically-valid methodology. Defs.’ Mem. at 8 (*citing Tyree v. Bos. Sci. Corp.*, No. 2:12-CV-08633, 2014 WL 5486694, at *41 (S.D.W. Va. Oct. 29, 2014) (excluding testimony of Dr. Iakovlev based on examination of sample of pathology slides selected by plaintiffs’ counsel)). Plaintiffs’ response to this argument—that Dr. Allison may offer case-specific testimony based on her review of pathology from the *Barker*, *Phelps*, and *Thompson* cases—misses the point. The challenge is not to her review of that case-specific pathology. Ethicon’s argument is that if Dr. Allison purports to offer any opinions based on her examination of the 60 to 90 other samples previously provided by plaintiffs’ counsel, her opinions are unreliable.

C. Dr. Allison’s Degradation Opinions Are Inadmissible Because She Cannot Link Them to Plaintiffs’ Alleged Injuries.

Ethicon also challenges Dr. Allison’s degradation opinions as unreliable because her admissions establish that there is “too great an analytical gap between the data [on which she relies] and the opinion proffered.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 519, 139 L. Ed. 2d 508 (1997). Her opinions about mesh degradation are only relevant if they can be linked to the symptoms Plaintiffs allege—and that link can only be made if it is based on reliable scientific evidence. *Id.* Dr. Allison admits that there are no scientific articles supporting her attempt to link the degradation she believes she has observed in her pathology reviews to Plaintiffs’ alleged symptoms. Defs.’ Mem. at 10 (citing Dr. Allison’s admissions that none of her

reliance materials establish to a reasonable degree of medical certainty that her posited *in vivo* degradation results in clinical symptoms).

Plaintiffs do not address these admissions, or Dr. Allison's inability to link her degradation opinions to Plaintiffs' alleged injuries. *See* Pls.' Opp'n at 8–10. They focus instead on the support for the degradation opinion alone. *Id.* (noting Dr. Allison's reliance on publications regarding, and her own observations of, alleged mesh degradation). This is insufficient, as it does not address Dr. Allison's inability to tie the purported degradation to alleged clinical outcomes. Dr. Allison cannot make this link, rendering her degradation opinions inadmissible. *Joiner*, 522 U.S. 136, 137 (1997) (“Nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”).

Plaintiffs also argue that Dr. Allison is qualified to testify regarding degradation, citing the Court's rulings that Drs. Trepeta and Iakovlev were so qualified in *Sanchez* and *Echnayem*. Pls.' Mem. at 9–10. Again, qualifications “do not guarantee reliability,” *Sanchez*, 2014 WL 4851989, at *6, as the Court's rulings in both cases demonstrate. *See id.* at *22–24 (excluding opinions of Dr. Trepeta); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 711 (S.D.W. Va. 2014) (excluding certain of Dr. Iakovlev's degradation-related opinions).

D. Dr. Allison's Degradation Opinions Are Unreliable Because She Did Not Address Alternative Potential Explanations for Her Observations.

As Ethicon explained in its memorandum, Dr. Allison did not account for the possibility that the “tree-barking” effect she attributes to polypropylene was the result of treatment of the pathology samples with xylene, rather than degradation of the mesh. Defs.' Mem. at 11–12. While Dr. Allison was aware that pathology samples are often treated with xylene, she was not aware of xylene's well-known tendency to dissolve polypropylene. *Id.* This failure to account for

this alternative explanation for what she concluded was mesh degradation renders her degradation-related opinions unreliable. *Id.*

Plaintiffs do not address this failure. Pls.' Mem. at 10–11. They merely assert that Dr. Allison “did consider whether the processing of tissue slides affects the polypropylene mesh fibers,” citing her testimony regarding processing with formalin (and, inexplicably, her testimony that she had no idea what xylene does to polypropylene). *Id.* at 11. Plaintiffs also cite Dr. Allison’s testimony regarding the “best study to evaluate this” and her testimony regarding a lack of contrary literature. *Id.* This testimony cannot be viewed as reliable given that Dr. Allison was completely unaware of the significance of xylene processing.

Dr. Allison’s lack of awareness of this fundamental characteristic of xylene, a solvent she knows is commonly used to process tissue samples, is yet another reason to exclude her degradation-related opinions as unreliable.

E. Dr. Allison’s Testimony Attributing Plaintiffs’ Pain to Entrapped Nerves Is Unreliable and Should Be Excluded.

Dr. Allison is well aware that only sensory nerves transmit pain. Defs.’ Mem. at 13. And she admits that she has no way of knowing whether entrapped nerves she saw in the pathology she reviewed were sensory nerves. *Id.* at 13–14. Yet she nonetheless purports to have concluded, to a reasonable degree of medical certainty, that the entrapped nerves she observed were the cause of Plaintiffs’ pain. *Id.* at 12–13. Her admissions establish that her opinions on this subject are without valid scientific support. *Id.* at 13–15. These opinions should therefore be excluded as unreliable.

In response, Plaintiffs assert that “[i]n essence, Ethicon argues that some nerves cause pain but just not these pelvic nerves.” Pls.’ Opp’n at 11. Not so. Ethicon argues that if Dr. Allison is going to attribute pain to nerves entrapped by the mesh, then she needs to be able to conclude to a reasonable degree of medical certainty that the nerves she observed are the type of

nerves that are capable of transmitting pain. If the entrapped nerves are autonomic or motor nerves, then, as Dr. Allison agrees, they cannot transmit pain and could not be a cause of the Plaintiffs' alleged pain. Defs.' Mem. at 13. Dr. Allison's admissions firmly establish that she cannot establish whether the nerves she observed are sensory, motor, or autonomic. Consequently, she has no basis for concluding that they are sensory and therefore capable of causing Plaintiffs' pain.

Plaintiffs' reliance on the Court's ruling in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *25 (S.D.W. Va. July 8, 2014), admitting Dr. Iakovlev's testimony that entrapped nerves can cause pain, is misplaced. There is no indication that the Court was presented with the argument differentiating the different types of nerves that might be entrapped, or that Dr. Iakovlev's testimony included admissions similar to those of Dr. Allison. The Court should evaluate Dr. Allison's proposed testimony based on the evidence relevant here. *Winebarger v. Bos. Sci. Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *4 (S.D.W. Va. Apr. 24, 2015) (counsel are "remiss" if they expect the Court to "align with . . . previous rulings when faced with a different record"). That evidence shows that Dr. Allison's opinions regarding entrapped nerves lack scientific support and are therefore inadmissible.

III. The Lack of Underlying General-Causation Testimony Renders Dr. Allison's Specific-Causation Testimony Inadmissible.

Even if an expert is identified solely as a specific-causation expert, and agrees to limit her testimony to those issues, she must nonetheless identify reliable general-causation testimony to support them. *In re Mirena IUD Prod. Liab. Litig.*, No. 13-CV-6586 (CS), 2016 WL 890251, at *39 (S.D.N.Y. Mar. 8, 2016) (an expert's "failure to offer or rely upon a general causation opinion renders his specific causation opinions without foundation and therefore inadmissible"). As this Court has made clear, "[E]stablishing general causation is an essential prerequisite to proving specific causation[.]" *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 605 (S.D.W. Va. 2013)

(citing *In re Bausch & Lomb Inc. Contact Lens Sol. Prod. Liab. Litig.*, MDL No. 1785, 2010 WL 1727807, at *2 (D.S.C. Apr. 26, 2010)). The underlying general-causation testimony can be the expert's own or that of another expert, but she must identify it before she formulates her specific-causation opinions—otherwise she cannot contend that she reached the latter using a scientifically valid methodology. *See, e.g., Mirena*, 2016 WL 890251 (excluding testimony of specific-causation expert who did not “offer[] a general causation opinion himself” and did not rely on plaintiff's general-causation experts “in forming his [specific-causation] opinion”).

As discussed, Dr. Allison cannot support her specific-causation opinions with reliable general-causation testimony, as is required. Defs.' Mem. at 15–17. Plaintiffs repeatedly assert that Dr. Allison is not offering general causation testimony. *E.g.*, Pls.' Opp'n at 1, 13 (“Dr. Allison is not a general causation expert.” (emphasis in original)). And given their refusal to allow Ethicon to take her general-causation deposition, fairness requires that she not be allowed to testify on general causation at trial. *Supra* Section I. Accordingly, she cannot point to general-causation opinions she herself developed to support her specific-causation testimony. And her general-causation opinions are unreliable in any event, for the reasons discussed above.

Nor can Dr. Allison point to the general-causation opinions of Plaintiffs' other experts as support for her specific-causation opinions, as her admissions establish that she did not review any of their reports before she developed her opinions (and still had not reviewed any of them at the time of her deposition). Defs.' Mem. at 16–17; *see also C.R. Bard*, 948 F. Supp. 2d at 605 (“[E]stablishing general causation is an essential prerequisite to proving specific causation.”). This lack of underlying general-causation opinions renders her specific-causation opinions inadmissible. *Id.* (excluding expert's specific-causation opinions for lack of a reliable general-causation predicate); *Mirena*, 2016 WL 890251, at *39.

Plaintiffs do not address Ethicon's argument that Dr. Allison may not offer specific-causation testimony unless she has established the required general-causation predicate. *See* Pls.' Mem. at 12–13. They do not address the holdings of the *Mirena* court, or this Court in *C.R. Bard. Id.* Plaintiffs merely reiterate that Dr. Allison is not offered as a general-causation expert—a point that supports Ethicon's argument—and that she is a “highly qualified pathologist”—a point that is irrelevant to Ethicon's argument. Pls.' Opp'n at 13.

The Court should find that Dr. Allison's specific-causation opinions lack the “foundational predicate” of a reliable general causation opinion, rendering her specific causation testimony “irrelevant” and inadmissible. *Mirena*, 2016 WL 890251, at *39. The Court should therefore exclude her specific causation testimony in its entirety.

CONCLUSION

Ethicon asks this Court to grant its Motion to Exclude the General Causation Testimony of Kimberly H. Allison, M.D., in its entirety for the reasons stated above and in Ethicon's memorandum in support of its motion.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Tel: 304.414.1800
dthomas@tcspllc.com

/s/ Christy D. Jones

Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Tel: 601.985.4523
christy.jones@butlersnow.com

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CERTIFICATE OF SERVICE

I certify that on May 15, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800